PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Jose REMACLE et al.

Confirmation No.: 7897

Application No.: 10/723,091

Art Unit: 1639

Filed: November 25, 2003

Examiner: Wessendorf, Teresa D.

For: METHOD FOR STABILIZING PROTEINS ON A MICRO-ARRAY

Attorney Docket No.: 4044.001

Customer No.: 000041288

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97 and §1.98

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the following documents for the above-identified application. Except for copies of documents corresponding to U.S. Patents and U.S. Patent Applications, copies of the documents set forth below and listed on the attached Form PTO/SB/08 and an European Search Report are provided herewith.

- 1. European Patent No. EP 0 336 231 A
- 2. U.S. Patent Publication No. US 2003/175827 A1
- 3. International Publication No. WO 93/07466 A
- 4. Great Britain Patent Application No. GB 2 016 687 A

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- 5. International Publication No. WO 03/050234
- 6. Japan Patent No. JP 61 189454 A (abstract)
- 7. Japan Patent No. JP 03 084461 A (abstract)

Document 1

European Patent Application No. EP 0 336 231 A entitled "Procedure for Stabilizing Biological Active Substances in Immobilized Form" published on October 11, 1989, in German.

In the European Search Report Document 1 was cited as in the "X" category of relevancy to claims 1-18.

Applicants are not aware of any English language document equivalent to Document 2, other than an English language abstract:

Biologically active substances which are intended, example, for immunodiagnosis and are in immobilized form must not lose their activity during the immobilization and the subsequent conversion into dry products and ought to retain their activity unchanged in the dried immobilized form for as long as possible. Dry products with improved activity and stability are prepared by drying the immobilized biologically active substances presence of a mixture of one or more sugar alcohols with a retarder, in particular of crystallization in the form hydrogenated oligosaccharides. Biochemistry, biotechnology and immunodiagnosis.

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Document 2

Document 2 is in the English language. In the European Search Report Document 2 was cited as in the "X" category of relevancy to claims 1-18.

Document 3

Document 3 is in the English language.

In the European Search Report Document 3 was cited as in the "X" category of relevancy to claims 1-18.

Document 4

Document 4 is in the English language.

In the European Search Report Document 4 was cited as in the "X" category of relevancy to claims 1-18.

Document 5

Document 5 is in the English language.

In the European Search Report Document 5 was cited as in the "X" category of relevancy to claims 1-18.

Document 6

Japan Patent No. JP 61 189454 entitled "Stabilized Immobilizing Antibody" published on August 23, 1986, in Japanese.

In the European Search Report Document 6 was cited as in the "X" category of relevancy to claims 1-18.

Applicants are not aware of any English language document equivalent to Document 6, other than an English language abstract:

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obtain a dried immobilizing antibody which maintains the initial enzyme activity without deterioration even after the long-term preservation at a room temp. and is convenient transportation, preservation, etc. by treating the immobilizing antibody with an aq. soln. contq. cane sugar or mannitol or a mixture composed thereof as a protective agent then drying the same thereby forming the antibody. CONSTITUTION: The immobilizing antibody is repeatedly subjected to the operation of bringing the immobilizing antibody into contact with the ag. soln. contg. the cane sugar or mannitol or the mixture composed thereof as the protective agent (the soln. contg a buffer soln. such as phosphoric acid-buffered physiological salt soln. as a solvent) and is then dried. The dried immobilizing antibody which maintains the initial enzyme activity without deterioration even after the long-term preservation at a room temp. and is convenient for transportation, preservation, etc. is thus obtd.

Document 7

Japan Patent No. JP 03 084461 entitled "Immunological Agglutination Reagent and Production Thereof" published on October 4, 1991, in Japanese.

In the European Search Report Document 7 was cited as in the "X" category of relevancy to claims 1-18.

Applicants are not aware of any English language document equivalent to Document 6, other than an English language abstract:

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PURPOSE: To improve the preservable stability of the above reagent by consisting the reagent of insoluble artificial carrier particles sensitized with an antigen or antibody, incorporating at least one kind of the compd. selected from albumin and dextran as stabilizer therein and freeze-drying the CONSTITUTION: Inorg. compd./dye composite particles having 1.2 to 2.0mum grain size and 1.2 to 2.0sp.gr. are preferable as the insoluble artificial carrier particles. Customary physically adsorbing the antigen or antibody to the carrier particles, etc., are used for the sensitization of the antiqen or antibody to the carrier particles. The albumins derived from man and bovine are more preferable as albumin to be used as the stabilizer. Dextrans of various mol.wt. are usable as the dextran if these dextrans are soluble in water. The content of the albumin and dextran is specified to about 3 to 20pts.wt. total of both per 5pts.wt. insoluble artificial carrier particles. The freeze-drying of the suspension of the immune material sensitized carrier particles added with the above- mentioned stabilizer is executed by the customary method.

The present Information Disclosure Statement is being filed after three months from the application's filing date and after the mailing date of the first Office Action on the merits, but before a final Office Action or Notice of Allowance (whichever is earlier) and, therefore, Applicants are filing concurrently herewith the Certification under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required.

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The submission of the listed document is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedated or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

Respectfully submitted,

Stephan A. Pendorf Reg. No. 32, 665

Pendorf & Cutliff 5111 Memorial Highway Tampa, Florida 33634-7356 (813)886-6085 Dated: June 20, 2005

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CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing INFORMATION DISCLOSURE STATEMENT Form PTO/SB/08A, including seven (7) documents, for U.S. Application No. 10/723,091 filed November 25, 2003, were deposited in first class U.S. mail, with sufficient postage, addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 20, 2005.

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

Stephan A. Pendor

PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0551-0331
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the a collection of information unless it contains a valid OMB control number. Substitute for form 1449/PTO Complete If Known **Application Number** 10/723,091 INFORMATION DISCLOSURE Filing Date November 25, 2003 STATEMENT BY APPLICANT First Named Inventor Jose REMACLE Art Unit 1639 **Examiner Name** (use as man sheets as necessary) Sheet 4044.001 Attorney Docket No.

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (If Known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 2003/175827 A1	09-18-2003	STILLMAN BRETT A	See transm. letter
		US-			
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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ^{5 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т
		EP 0 336 231 A	10-11-1989	BEIER WILFRIED	See transm. letter	N
		WO 93/07466 A	04-15-1993	DEVEREAUX SHARON M	See transm. letter	Y
		GB 2 016 687 A	09-26-1979	ABBOTT LAB	See transm. letter] Y
		WO 03/050234	06-19-2003	SANDFORD ANDREW F	See transm. letter] Y
		JP 61 189454 A (abstract)	08-23-1986	KATSUKI SHOJI	See transm. letter	Y
		JP 03 084461 A (abstract)	04-10-1991	TAJIMA MASAKAZU	See transm. letter	Y

Examiner Signature	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.